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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,879	07/28/2003	Michael M. Sekar	ABIOS.001A	3875

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EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,879	SEKAR ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 29, 2005 has been entered.
2. Applicant's amendment of claim 1 is acknowledged and has been entered.
3. Claims 1-21 are currently pending

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9, 11-19, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over French et al [US 6,297,018] in view of Lee et al [Lee et al, A fiber-optic microarray biosensor using aptamers as receptors, 2000, Anal Biochem, 282:142-146].

With respect to claims 1, 2, French et al teach assays detecting nucleic acid targets with primers involving the use of polarization or anisotropy (column 8, lines 15-28) of luminophores and fluorophores (column 20, lines 63-67). French et al teach that the signal is observed by measuring intensities of luminescence emissions parallel and perpendicular to an excitation

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polarization, and then using these quantities to evaluate a suitable mathematical function such as polarization or anisotropy (column 8, lines 20-27). French et al further teach the attachment of the components to a solid support such as a bead or surface (column 12, lines 11-18), since an increase in polarization is observed when including a mass label, such as beads (column 8, lines 60-64). French et al do not specifically teach that the primers are aptamers.

Lee et al, however, do teach a method of measuring an analyte using a system comprising DNA aptamers immobilized on the surface of silica beads (p. 143, col. 1) and making fluorescent measurements. Lee et al further teaches that this system shows selectivity for its target and can be reused with good reproducibility, allows for the possibility for multianalyte detection (p. 146, col. 1, lines 19-30).

Therefore it would have been obvious in the method of French et al to use aptamers, as suggested by Lee et al, in order to provide an assay for onco-protein and disease related protein detection that is quick, sensitive, convenient, and selective in the assays of French et al.

6. With respect to claim 3, Lee et al teach silica beads (p. 143, col.1).

7. With respect to claims 4-5, the beads taught by Lee et al have a diameter of 3.1 μm (p.143, col.1).

8. Furthermore, although Lee et al do not teach beads with a diameters of 5 μm , it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. With respect to claim 6, French et al teach mixing the materials in a solution, as well as attaching one or more components to a solid support such as a bead or surface (column 12, lines 11-19).

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10. With respect to claims 7, 11, 12, French et al teach the assay may be performed on DNA arrays with multiple assay sites (column 39, lines 30-46). Lee et al also teach that the beads with attached aptamers are arranged on microwell arrays, with multiple microwells containing the beads (p. 143, col.2).

11. With respect to claim 8, Lee et al teach that the aptamers are 15-mer single stranded DNA that bind to thrombin (p.143, col.1).

12. With respect to claim 9, French et al teach the use of fluorescein (column 39, lines 25-27).

13. With respect to claim 13, each addressable location of the biosensor taught by Lee et al comprises thrombin aptamer beads (p. 144, col.2).

14. With respect to claims 14, 15, French et al teach that multiple labels may be used depending on the number of alleles corresponding to the polymorphism of interest (column 9, lines 46-67).

15. With respect to claim 16, French et al teach that the polarized light may come from a laser (column 25, lines 59-67).

16. With respect to claims 17, 18, 21, French et al teach that the assays may be used for finding SNPs related to particular diseases (column 13, lines 60-67), where the samples come from human subjects (column 10, lines 46-56).

17. With respect to claim 19, French et al teach that the target molecule may also be proteins (column 48, lines 45-47).

18. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over French et al [US 6,297,018] in view of Lee et al [Lee et al, A fiber-optic microarray biosensor using aptamers as

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receptors, 2000, Anal Biochem, 282:142-146], and further in view of Lakowicz et al [US 5,631,169].

French et al and Lee et al teach a method involving the use of fluorescein, as discussed above. Neither French et al nor Lee et al teach the use of carboxyfluorescein

Lakowicz et al, however, do teach the use of carboxyfluorescein, which has the advantage of long lifetimes, which may allow for easy suppression of the autofluorescence of biological samples (column 4, lines 1-15).

Therefore it would have been obvious in the method of French et al and Lee et al to use carboxyfluorescein, as suggested by Lakowicz, in order to have fluorophores with long lifetimes, which may allow for easy suppression of the autofluorescence of biological samples.

19. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over French et al [US 6,297,018] in view of Lee et al [Lee et al, A fiber-optic microarray biosensor using aptamers as receptors, 2000, Anal Biochem, 282:142-146], and further in view of Gold et al [US 6,544,776].

While French et al and Lee et al teach a method for the detection of analytes, they do not specifically teach the detection of metabolites.

Gold et al, however, teach that the detection of the pattern and level of target molecules (column 3, lines 1-11) such as metabolites (column 4, lines 45-58) using techniques such as fluorescence anisotropy (column 16, lines 30-35) allow for the screening of individuals at risk for developing a particular disease.

Therefore it would have been obvious in the method of French et al and Lee et al to detect metabolites, in order to allow for the screening of individuals at risk for developing a particular disease using the assays of French et al and Lee et al.

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Response to Arguments

20. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641
7/11/05